Claims 1 through 16, 19 through 22 and 25 through 27 are pending in this application. Applicant inadvertently incorrectly amended claims 16 and 21 in the amendment filed on September 23, 2002. Applicant has amended claims 16 and 21 to eliminate any overlap of corn strain recited. In addition, applicant has added new claims 26 and 27 to include the corn strain incorrectly recited in amended claims 16 and 21. Applicant submits no new matter is introduced by the amendments of the claims or the addition of the new claims.

THE EXAMINER'S REJECTION BASED ON 35 USC § 101

The Examiner has rejected claims 1 through 15, 19 through 20, 22 and 25 under 35 USC § 101 because he believes the claimed invention is not supported by either a specific assertive utility, a credible assertive utility or a well established utility.

An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (i.e., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible. MPEP § 2107.

Applicant submits a person of ordinary skill in the art will immediately appreciate the usefulness of an invention which eliminates the laborious, time-consuming and variable results of methods which introduce foreign, i.e. non-indigenous, DNA, into plant cells and provides a method for producing transgenic plants by introducing therein foreign mRNA. The resulting transgenic plant produced by the method of the present

invention is capable of synthesizing a protein in subsequent generations of plants based on the transfer of genetic information via mRNA molecules.

Genetically transformed plants which produce highly desirable proteins are economically important and commercially desirable. One of skill in the art would appreciate the amount of work that is eliminated using the method of the present invention to obtain the proteins (i.e., soy globulin protein) and the commercial viability of the method of the present invention based on the viability of the resultant protein.

ii. An application should not be rejected for lack of utility if it asserts a useful invention for any practical purpose (i.e., it has a specific and substantial utility) and the assertion would be considered credible by a person of ordinary skill in the art.

Courts have noted that adequate proof of any pharmacological activity of a compound constitutes a showing of practical utility. Cross vs. Iizuka, 753 F.2d 1040, 224 USPQ 739 (CAFC 1985), see also, Nelson v. Boler, 626 F.2d 853, 206 USPQ 881 (CAFC 1980). Pharmacological activity refers to the properties and reactions of drugs, especially with relation to their therapeutic value. Cross at 1046. Courts have accepted evidence of in-vitro utility as sufficient to establish a practical utility without a rigorous correlation to in-vivo testing where the disclosure of pharmacological activity is reasonable based upon probative evidence. Cross at 1050. "We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in-vitro testing, may establish a practical utility for the compound in question." Cross at 1051, see also, Fujikawa v. Wattanasin , 39 USPQ 2d 1895 (CAFC 1996).

Applicant respectfully submits the pharmacological activity, as illustrated in figures 1 through 6, in addition to the discussion in the specification, clearly establishes that the invention has a particular practical purpose. Specifically, the method of the present invention claims how to obtain a valuable protein, having a practical utility, by the use of a transgenic plant. The pharmacological activity illustrated in the figures by the immunoassays support the practical purpose of the invention.

Applicant respectfully submits that the United States Patent and Trademark Office has recognized the significance of the present invention in U.S. Patent No. 6,198,025 which has identical figures and specification but claims the resultant corn plant and corn kernels which express the soy globulin protein by use of the method of the present invention. Applicant submits it is contradictory for the United States Patent and Trademark Office to recognize and appreciate the value of a transgenic corn plant and corn kernels but not to appreciate the method which produced the transgenic corn plant and corn kernels.

Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record, i.e., test data, affidavits or declarations from experts in the art, patents or printed publications that are probative of the applicant's assertions. Applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement. MPEP § 2107.

The Examiner states a credible assertive utility is not established because the facts upon which the assertion is based are inconsistent with current scientific dogma.

The Examiner further asserts that based upon the recited scientific articles, the microinjection method used in the application is not viable.

The examiner asserts the method of the present invention is not viable based on the recited reference by Hansen. The Hansen reference gives a general survey of transformation methods at the time the article was written. The article does not mention the use of transformation based on mRNA in either a positive or negative association. More importantly, the Hansen reference encourages research in the area of transformation and specifically recognizes the problem in plant transformation which the current invention overcomes. Specifically, on page 229, first column, in the third full paragraph, the article states "there is considerable interest in developing plant transformation methods that exclude the tissue culture steps and rely on a simple protocol." This is one of the main advantages of the method of the present invention; it is simple, yet clearly has yielded a plant with the genetic factors which can be expressed, i.e., the production of soy globulin.

The Hansen reference suggests that what the method of the present invention achieves is desired in the industry. On page 230, first column, second full paragraph, the article states "the perfect transformant would contain a single copy of the transgene that would segregate as a mendelian trait, with uniform expression from one generation to the next." The ability to replicate from mRNA rather than using the full complement of DNA is specifically the objective Hansen is requesting in the passage.

Hansen specifically acknowledges and appreciates the complexity in the molecular workings of a plant. On page 228, second column, first full paragraph, the

article states, "molecular analysis of plants obtained by biolistic transformation (i.e., use of microinjection) generally reveals a complex pattern of transgene integration." Thus, the "inner workings" of the transformation are not known, but the methods to obtain the desired product, i.e. a transgenic plant, are certainly appreciated by Hansen and those skilled in the art.

Finally, Hansen specifically discusses the use of corn as a transgenic plant in the first paragraph of the article. This gives credibility to the use of corn plants in transformation protocols.

Applicant respectfully submits that the Hansen article not only encourages but supports the assertion of a practical utility for the present invention in addition to supporting a credible utility for the present invention.

The examiner asserts that the Songstad article prohibits the use of microinjection in transgenic plants. Applicant respectfully disagrees with the examiner's understanding of the Songstad article.

The Songstad article clearly discusses the feasibility of microinjection using full DNA on page 10, first column. The Songstad article and the specification of the application appreciate the difficulty in introducing foreign DNA into protoplasts to enable introduction into the nucleus to obtain a transgenic plant. However, the techniques in Songstad are not using mRNA but the full complement of DNA and therefore are not analogous to the techniques of the method of the present invention. Further, none of the recited information discusses corn plants or the particular strain of corn being used in the present invention.

The applicant directs the examiner's attention to the articles listed on pages 1 and 2 of the specification which clearly illustrate the success of Dr. Niu, and his procedures, using mRNA for microinjection of plants. As all of these articles have been published in reputable science journals, the respect for the work of Dr. Niu is certainly appreciated by those of ordinary skill in the art.

As the use of mRNA is not discussed in the Songstad article, applicant submits that the problems asserted by the examiner could be overcome by the use of mRNA rather than the full complement of DNA. Further, applicant again points to the successful production of soy globulin protein, as illustrated in figures 1 through 6, which confirm the use of microinjection for the method of the present invention.

On the top of page 5 of the Official Action, the examiner states the inventor does not teach how to express only one beneficial protein but rather how to express the putative soy globulin protein. In addition, the examiner states the inventor does not address what precautions must be taken to avoid RNA degradation by RNAses which are imminent. Lastly, the examiner states, the inventor does not teach how the corn kernels generate DNA which is supposedly integrated into the host gene from an RNA template; producing only one species of DNA from the population of RNA molecules isolated from the soy plant.

Applicant submits that the present invention does not claim "one beneficial protein" but rather has claimed a method which produces a transgenic plant that produces soy globulin protein. Applicant submits that the invention does not teach how

to obtain a "particular beneficial protein" because the subject of the invention is a method to produce a transgenic plant which produces soy globulin protein.

The applicant submits that the inventor has not addressed what precautions need to be taken to avoid RNA degradation because this was not found to be a problem in the method of the present invention. Applicant submits that the method in the present invention is successful, as illustrated by the immunoassays of figures 1 through 6, and the issues of mRNA degradation are moot in the present invention.

Finally, the Examiner states that the present invention does not teach how the corn kernels generate DNA in the transgenic plant. Applicant submits it is well settled patent law that an inventor does not need to know the why of the scientific and technological principles underlying an invention. As discussed above, the Hansen article, which the examiner has placed a great deal of support for his argument for lack of utility, appreciates the complexities of molecular biology without having a "step by step" recitation of the inner workings at the molecular level. As such, it is not necessary for the applicant to explain how the introduction of the mRNA generates DNA in the transgenic plant.

Applicant respectfully submits that the examiner has not established a *prima facie* case of lack of utility of the method of the invention and therefore, based on the reasoning and evidence submitted herewith and in the response dated September 23, 2002, applicant respectfully submits the rejection should be withdrawn.

THE EXAMINER'S REJECTION BASED ON 35 USC § 112

The Examiner has rejected claims 1-15, 19-20 and 25 under 35 U.S.C. §112, first paragraph, as allegedly failing to be commensurate in scope with the instant specification.

To be enabling under 35 U.S.C. § 112, a patent must contain a written description that enables one skilled in the art to make and use the claimed invention without undue experimentation. Atlas Powder Co. v E.I. Du Pont De Nemours & Co., 224 USPQ 409, 413 (CAFC 1984). "An inventor need not, however, explain every detail since he is speaking to those skilled in the art" DeGeorge v Bernier, 226 USPQ 758. Therefore, with regard to the written description requirement, applicant wishes to point out that it is well settled case law that the claimed subject matter need not be set forth "literally or *in haec verba*" in order for the specification to satisfy the written description requirement of 35 U.S.C. §112, first paragraph. In re Lukach, 169 USPQ 795. All that is required for an adequate written description is that the specification "convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that the applicant has invented the specific subject matter later claimed" In re Wertheim, 191 USPQ90,97).

Regarding the examiner's question pertaining to the precautions utilized to prevent the degradation of mRNA during microinjection, applicant reiterates that methods for preventing RNA degradation are well known to those of skill in the art and are set forth in Protocols in Molecular Biology by Maniatis et al. as well as in Current Protocols in Molecular Biology by Ausubel et al., eds (1995).

The examiner asserts that it is not clear how the mRNA molecules were transported to the nucleus. However, "an inventor need not know the why of the

scientific and technologic principles underlying an invention." Diamond Rubber Co. v Consolidated Rubber Tire Co., 220 U.S. 428, 435-36 (1911). Furthermore "An inventor is not required to understand the theory of how his invention works, so long as his patent adequately discloses to a person of ordinary skill in the art how to make and use the invention."

An inventor is not responsible for the correctness of his theories and explanations when their correctness is not related to the validity of claims under consideration. In other words, an inventor "is entitled to protection for the merits of his invention, even when they surpass his expectations or go beyond what was known or commercially available at the time of the invention." Micro Motion Inc. v Exac Corp., 16 U.S.P.Q.2d 1001 (1990). When transport of RNA molecules both into and out of the nucleus has been described in the literature, applicant is not required to provide an explanation or mechanism for such transport. The data presented in Figure 6 clearly show incorporation of soy DNA into the genome of the transgenic corn plants. The fact that the Southern is positive for soy DNA indicates that the injected mRNA molecules were indeed transported into the nucleus, reverse transcribed and inserted into the maize genome. The western blots shown in Figure 5 indicate that not only was the DNA incorporated into the maize genome, it was expressed and soy globulin protein was detected. Again, these experiments were performed against the proper negative controls.

The examiner appears to require that applicant isolate reverse transcriptase from plants and show the synthesis of cDNA using the same. This requirement is respectfully submitted to be untenable and unsupported by relevant patent law as set

forth above. Applicant thoroughly described the methodology utilized and the results obtained during the generation of the transgenic corn plants of the invention. See pages 9-18 and Figures 1-6.

Applicant respectfully traverses the rejection under 35 U.S.C. §112, first paragraph based on the reasoning and evidence submitted herewith and in the response dated September 23, 2002. Applicant respectfully submits the rejection should be withdrawn.

CONCLUSION

It is now believed that all of the claims in this application are allowable and the present invention is an advance over the prior art. The amendments to the claims are fully supported by the application as filed, and no new matter is being introduced. Therefore, applicant submits that the rejections have been overcome; the application should thus proceed to allowance and issue.

Respectfully submitted,

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Rhonda Bryant
(signature)

BY: RHONDA BRYANT

DATE: 4 OCTOBER 2002

ATTACHMENT A

C1 16. (Amended) A transgenic corn plant expressing soy globulin protein, wherein said corn is strain 27-1.

C2 21. (Amended) Transgenic corn kernels expressing soy globulin protein, wherein said corn is strain 27-1.

C3 26. (New) Transgenic corn kernels expressing soy globulin protein, wherein said corn is strain 85089 .

27. (New) Transgenic corn kernels expressing soy globulin protein, wherein said corn is strain 85089 .

ATTACHMENT B

16. (Amended) A transgenic corn plant expressing soy globulin protein, wherein said corn is strain 27-1[, wherein said corn is strain 85089].

21. (Amended) Transgenic corn kernels expressing soy globulin protein, wherein said corn is strain 27-1[, wherein said corn is strain 85089].

ATTACHMENT C

1. A method for producing transgenic plants which express beneficial exogenous proteins, comprising:
   a. obtaining a sample of mRNA encoding said exogenous protein;
   b. incubating seed of said plant with said mRNA under conditions whereby said mRNA enters said seed;
   c. germinating said seed; and
   d. growing said transgenic plant from said seed.
2. A method as claimed in claim 1, wherein said exogenous protein is soy globulin.
3. A method as claimed in claim 1, wherein said mRNA encodes soy globulin.
4. A method as claimed in claim 1, wherein said seed is corn seed.
5. A method as claimed in claim 1, wherein said exogenous protein is detected with methods selected from the group consisting of Western blotting, double agar immunodiffusion, and Sodium dodecyl sulfate polyacrylamide gel electrophoresis.
6. A method as claimed in claim 1, wherein said mRNA is introduced into said seeds by microinjection.
7. A method as claimed in claim 1, wherein said mRNA is isolated from soy cotyledon.
8. A method as claimed in claim 1, wherein said mRNA is isolated from soy sprouts.
9. A transgenic plant expressing beneficial exogenous proteins, produced by a method comprising:
   a. obtaining a sample of mRNA encoding said exogenous protein;
   b. incubating seed of said plant with said mRNA under conditions whereby said mRNA enters said seed;

c. germinating said seed; and

d. growing said transgenic plant from said seed.

10. A method of producing transgenic corn plants expressing soy globulin, comprising:

a. obtaining soy globulin encoding mRNA;

b. incubating corn seed with said mRNA under conditions whereby said mRNA enters said corn seed;

c. germinating said corn seed treated as in step b;

d. growing a plant from said germinated seed; and

e. detecting said soy globulin in said transgenic corn plant.

11. A method for producing transgenic corn plants expressing soy globulin protein, comprising:

a. obtaining seed from corn strain 27-1 and imbibing said seed in double distilled water for at least 48 hours;

b. isolating and purifying soy globulin mRNA from soy cotyledon;

c. microinjecting 1μg/μl of said purified mRNA into said seed;

d. germinating said seed; and

e. growing transgenic corn plants from said seed, said transgenic plant producing said soy globulin protein.

12. A method for producing transgenic corn plants expressing soy globulin protein, comprising:

a. obtaining seed from corn strain 85089 and imbibing said seed in double distilled water for at least 48 hours;

b. isolating and purifying soy globulin mRNA from soy cotyledon;

c. microinjecting 1µg/µl of said purified mRNA into said seed;

d. germinating said seed; and

e. growing transgenic corn plants from said seed, said transgenic plant producing said soy globulin protein.

13. A method for producing transgenic corn plants expressing soy globulin protein, comprising:

a. obtaining seed from corn strain 27-1 and imbibing said seed in double distilled water for at least 48 hours;

b. isolating and purifying soy globulin mRNA from soy sprout;

c. microinjecting 1µg/µl of said purified mRNA into said seed;

d. germinating said seed; and

e. growing transgenic corn plants from said seed, said transgenic plant producing said soy globulin protein.

14. A method for producing transgenic corn plants expressing soy globulin protein, comprising:

a. obtaining seed from corn strain 85089 and imbibing said seed in double distilled water for at least 48 hours;

b. isolating and purifying soy globulin mRNA from soy sprout;

c. microinjecting 1µg/µl of said purified mRNA into said seed;

d. germinating said seed; and

e. growing transgenic corn plants from said seed, said transgenic plant producing said soy globulin protein.

15. A transgenic corn plant expressing soy globulin protein, produced by a method comprising:

a. obtaining seed from corn strain 27-1 and imbibing said seed in double distilled water for at least 48 hours;

b. isolating and purifying soy globulin mRNA from soy sprout;

c. microinjecting 1µg/µl of said purified mRNA into said seed;

d. germinating said seed; and

e. growing transgenic corn plants from said seed, said transgenic plant producing said soy globulin protein.

16. (Twice Amended) A transgenic corn plant expressing soy globulin protein, wherein said corn is strain 27-1.

19. The transgenic plant of claim 9 in which said seed is corn strain 27-1.

20. The transgenic plant of claim 9 in which said seed is corn strain 85089.

21. (Twice Amended) Transgenic corn kernels expressing soy globulin protein, wherein said corn is strain 27-1.

22. Kernels from a transgenic corn plant expressing soy globulin protein, produced by a method comprising:

a. obtaining seed from corn strain 27-1 and imbibing said seed in double distilled water for at least 48 hours;

b. isolating and purifying soy globulin mRNA from soy sprout;

c. microinjecting 1µg/µl of said purified mRNA into said seed;

d. germinating said seed;

e. growing transgenic corn plants from said seed, said transgenic plant producing said soy globulin protein; and

f. harvesting said kernels from said transgenic corn plants expressing soy globulin protein.

25. Kernels expressing soy globulin protein from a transgenic corn plant produced by a method comprising:

a. obtaining seed from corn strain 27-1 and imbibing said seed in double distilled water for at least 48 hours;

b. isolating and purifying soy globulin mRNA from soy sprout;

c. microinjecting 1µg/µl of said purified mRNA into said seed;

d. germinating said seed;

e. growing transgenic corn plants from said seed, said transgenic plant producing said soy globulin protein; and

f. harvesting said kernels from said transgenic corn plants.

26. (New) Transgenic corn kernels expressing soy globulin protein, wherein said corn is strain 85089 .

27. (New) Transgenic corn kernels expressing soy globulin protein, wherein said corn is strain 85089 .